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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/713,889 | 11/14/2003 | Benjamin Levinson | WELLSP 3.0-003 | 1106 |
| 48394 | 7590 | 01/11/2007 | | |
| DIEHL SERVILLA LLC 77 BRANT AVE SUITE 110 CLARK, NJ 07066 | | | EXAMINER KRISHNAN, GANAPATHY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/713,889 | Applicant(s) LEVINSON ET AL. | |
| | Examiner Ganapathy Krishnan | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,8-31 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,8-31 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/3/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 10/13/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1, 6-7 and 32-33 have been canceled.
2. Claims 2, 5, 11, 19, 21-23, 26, 29-30 and 34 have been amended.
3. Remarks drawn to claim objections and rejections under 25 USC 112, first and second paragraphs, 102 and 103.

Claims 2-5, 8-31 and 34-37 are pending in the case.

Claim Objections

The objection to claims 2, 21 and 23 have been overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-5 and 8-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been overcome by cancellation of claim 1 and deletion of the recitation, "wherein the tin mesoporphyrin is not derivatized with a complexing agent" in claims 5 and 11.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The rejection of Claims 1-5 and 8-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention advanced earlier has been overcome by cancellation of claim 1 and amendments to claims 23 and 26.

The following new rejection is made of record.

Claims 21, 23-28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites at line 5, subjecting the tin mesoporphyrin formate to a chemical metal insertion process with a metal halide and further recites, to obtain a tin mesoporphyrin halide. The tin mesoporphyrin formate is subject to a metal insertion and still produces tin mesoporphyrin halide? It is not clear what applicants intend.

According to the method of claim 23, the starting material is hemin. The claim recites that it is reacted with hydrogen and a catalyst to obtain a metal mesoporphyrin formate. Is the iron in the hemin replaced by another metal in this step? The formate is further subjected to a metal insertion process to obtain a metal mesoporphyrin halide. Is this a new metal that is replacing the metal in the previous step? It is not clear what applicants intend.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 22 and 30 under 35 U.S.C. 102(b) as being anticipated by Kappas et al (US 4,692,440) has been overcome by amendment.

The following art rejection is made of record necessitated by amendment.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Goel et al (WO 97/05152; document cited in IDS of 10/3/2006).

Goel et al teach a pharmaceutical composition comprising a complex of a cobalt mesoporphyrin (a metal mesoporphyrin) complexed to an amino acid (page 37 line 1 through page 39 line 10; page 49, lines 6-28). This is seen to meet the limitations of instant claim 29.

Claim 29 is a product by process claim, which is a product claim.

Product-by-Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31, which depends from claim 23 was inadvertently included in this rejection in the previous office action even though there was no art rejection for claim 23.

The rejection of Claims 2-5, 8-10, 22, 29-30 and 34-37 under 35 U.S.C. 103(a) as being unpatentable over Robinson (US Patent Pub. No. 2003/0100752) in combination with Drummond (Annals of New York Academy of Sciences, 1987, 514, 87-95) and Bettelheim et al (General, Organic and Biochemistry, 1998, page 596) and the rejection of Claims 11-20 under 35 U.S.C. 103(a) as being unpatentable over Niedballa et al (US 5,275,801) are both being maintained for reasons of record.

Regarding claims 2-5, 8-10, 22, 29-30 and 34-37 applicants argue that Robinson is directed to a broad genus of porphyrin and according to Robinson compounds with high water solubility are not taken up efficiently by tumor cells and Robinsons compounds need a surfactant to make them water soluble. Drummond and Robinson are also silent regarding this point. Robinson and Drummond also deal with treatment of psoriasis and heme metabolism respectively and there is no commonality between the two treatments. Combination of this teaching with that of Bettelheim just points to the fact that the compounds of Robinson when combined with amino acids renders them water soluble and there is not motivation to combine since Robinson teaches that the compounds should be lipophilic.

This is not found to be persuasive.

Robinson teaches that one of the preferred metal ions complexed to the core is Tin (page 32, paragraph 183) and the compounds of Robinson are complexed to amino acids. Robinson, at paragraph 211 states that exemplary compounds include solutions of the new compounds in solvents, most preferably water. This means that the compounds are water soluble. Robinson additionally states at paragraph 208 that solutions of the compounds can be made in water suitably mixed with a surfactant. This does not mean that the surfactant is needed to make them water soluble. The statement by Robinson that water soluble compounds are not taken up efficiently by tumor cells does not mean that they are not taken up at all. Robinsons application may be different but his teaching shows that these compounds are water soluble including the tin porphyrins as instantly claimed.

Drummond, drawn to metalloporphyrins, teaches control of heme metabolism using tin-protoporphyrins (page 87, introduction, last paragraph). Tin protoporphyrin was by far the most potent (page 88, Results and Discussion; page 89). Tin protoporphyrin is structurally similar to tin-mesoporphyrin except that the protoporphyrin has an ethylene side chain. In the mesoporphyrin, the ethylene side chain is saturated. According to Robinson (above), the side chain can be an alkenyl. When it is alkenyl, the structure is similar to the protoporphyrin as taught by Drummond. According to Drummond, tin-protoporphyrins have proved to be innocuous in toxicology studies in animals. Long-term treatment of rats with tin-protoporphyrins resulted in decrease in bilirubin levels (page 90, middle paragraph; page 92, first full paragraph). From this it is seen that tin porphyrins, which are water soluble according to Robinson are also potent in controlling heme metabolism. Robinson need not necessarily teach this fact. Since

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Bettelheim teaches that amino acids are zwitterionic and renders them water soluble it is logical to complex the porphyrins with them to increase the water solubility. Hence there is motivation to combine.

Regarding claims 11-20 applicants argue that Niedballa is directed to hematoporphyrins and deuteroporphyrins and fails to suggest a tin mesoporphyrin complex with an amino acid as recited in instant claim 11 and there is no teaching regarding the ratios as instantly claimed.

This is not found to be persuasive.

Niedballa teaches all of the important steps as instantly claimed for making a porphyrin core which includes tin as the central metal ion and also states that secondary reactions like hydrogenation, esterification, and alkylations are all performed according to literature processes known to one of skill in the art (col. 11, lines 3-7). The method of Niedballa is a general one and can be applied to the porphyrin core. The yields are also high. Hence there is motivation to sue the method of Niedballa.

Conclusion

Claims 2-5, 8-31 and 34-37 are rejected


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623